

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Jude Sauer

SERIAL NUMBER: 10/056,473

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FOR: VASCULAR HOLE CLOSURE

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) Group Art Unit: 3734
)
) Before the Examiner:
) Lindsay M. Bachman
)
) Confirmation No. 5120
)

Commissioner for Patents
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APPEAL BRIEF

(1) REAL PARTY IN INTEREST

The real party in interest is Interventional Therapies.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that may have a bearing on the present appeal.

(3) STATUS OF CLAIMS

Claims 5-13, 20-21, 23-40, 42-45 and 51-58 are currently pending in the present application. A Final Office Action issued on July 12, 2007, rejecting the referenced claims. The Applicant filed a Notice of Appeal on November 12, 2007. Applicant appeals from the final rejection of the referenced claims.

(4) STATUS OF AMENDMENTS

No amendments have been made subsequent to the July 12, 2007 Final Office Action.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

Seven independent claims are involved in the present appeal. Each claim will be described in turn.

Independent claim 11 is reproduced below:

11. A surgical apparatus for closing a wound, the surgical apparatus comprising:

a tongue member having a distal section insertable into a wound and having an opening through a portion of said distal section; and

a face opposing the distal section of the tongue member and separated from the distal section of the tongue member by a gap, the face having an area large enough to impede further insertion of the apparatus into the wound, further comprising a sleeve holder positioned within the distal section of the tongue member, the sleeve holder including first and second sleeves disposed

within the sleeve holder, said first and second sleeves being joined by a length of suture material.

Independent claim 11 relates to a surgical device that includes a tongue member 36 with a distal portion that is insertable into a wound. The tongue member has an opening 39 through the distal section to permit a guide wire to be fed therethrough. See Figures 4A and 5 and paragraph 0049 for an example.

The device of claim 11 also includes a gap having a face that impedes insertion of the device into the wound (for facilitating placement) and two sleeve, or ferrule, holders 40 in a distal section of the tongue member housing two sleeves 70, 72, or ferrules, joined by a length of suture 75. See Figures 4A and 4B and paragraph 50.

Independent claim 12 is reproduced below:

12. A surgical apparatus for closing a wound, the surgical apparatus comprising:

a tongue member having a distal section insertable into a wound; and

a face opposing the distal section of the tongue member and separated from the distal section of the tongue member by a gap, the face having an area large enough to impede further insertion of the apparatus into the wound, further comprising a guide wire tube disposed through an elongate body assembly, a distal end of the guide wire tube being disposed adjacent a distal opening of the tongue member.

Independent claim 12 relates to a surgical device that includes a tongue member 36 with a distal portion that is insertable into a wound. The device has a guide wire tube 82 that permits a guide wire to be fed therethrough. The distal end of the guidewire tube 82 is adjacent to a distal opening 39 of the tongue member. See Figures 4A and 5 and paragraph 0049 for an example.

The device of claim 11 also includes a gap having a face that impedes insertion of the device into the wound (for facilitating placement). See Figures 4A and 4B and paragraph 50.

Independent claim 53 is reproduced below:

53. A tip for a surgical apparatus, the tip having a longitudinal axis, a distal end, and a proximal end, the tip further comprising:

a window for receiving tissue;

a first wall at a proximal end of the window, the first wall disposed at an angle to the longitudinal axis, the angle selected to impede insertion of the tip into a wound; and,

a second wall disposed at an angle to the longitudinal axis at a distal end of the window, further comprising a tongue having an opening through a portion of a distal tongue section, a base of the tongue forming a bottom portion of the window.

Independent claim 53 describes a tip for a surgical device, the tip including a window 15 for receiving tissue, a first wall 48 at a proximal end of the window, the first wall having an angle that impedes further insertion of the tip, and a second wall 46 disposed at an angle. The tip further includes a tongue 36 that has an opening 39 through a distal portion thereof to permit receipt of a guidewire. A base part of the tongue forms a bottom portion of the window 15. See Figures 4A, 4B and 5 and paragraphs 0047 and 0049.

Independent claim 51 is reproduced below:

51. A surgical apparatus comprising a tip, the tip having a longitudinal axis, a distal end, and a proximal end, the tip further comprising:

a window for receiving tissue;

a first wall at a proximal end of the window, the first wall disposed at an angle to the longitudinal axis, the angle selected to impede insertion of the tip into a wound; and,

a second wall disposed at an angle to the longitudinal axis at a distal end of the window, further comprising a ferrule holder, the ferrule holder including the second wall, further comprising a tongue extending between the first and second walls, wherein the ferrule holder includes

projections receivable within grooves of the tongue for retaining the ferrule holder on the tongue.

Independent claim 51 relates to a surgical device having a tip that includes a window 15 for receiving tissue, wherein one wall 48 of the window is disposed at an angle relative to the device's longitudinal axis, which angled wall impedes insertion of the device (to facilitate positioning). A second wall 46 of the window is disposed at an angle and includes a ferrule holder 40, which ferrule holder includes projections 41 receivable on the tip's tongue 36 for retaining the ferrule holder 40 on the tongue. See Figures 4A and 4B and paragraphs 0047-0049.

Independent claim 40 is reproduced below:

40. A surgical apparatus comprising:

a body portion having a distal end and a proximal end;

a tubular portion having a distal end and a proximal end, the proximal end of the tubular portion attached to the distal end of the body portion; and,

a lever having a distal end and a proximal end, the distal end of the lever operatively coupled to the distal end of the body portion, wherein the lever has a generally U-shaped cross-section relative to the perpendicular of the longitude of the body portion with a flat surface of the lever lying substantially flush with the body portion in a closed position of the lever.

Independent claim 40 relates to a surgical device having a body portion 212, a tubular portion 210 attached to the body portion, and a lever 214, the distal end of the lever coupled to the distal end of the body portion. The lever has a generally U-shaped cross section that is perpendicular to the longitudinal axis of the device, with a flat surface of the lever lying substantially flush with the body portion when in a closed position. Reference is made to Figure 13 and paragraph 0069.

(6) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The following issues are drawn from the last Final Office Action on the merits dated July 12, 2007:

- (A) Claims 11-13 and 51-58 have been rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,431,666 to Sauer (hereinafter “the ‘666 patent”);
- (B) Claims 5-10 and 42-45 were rejected under 35 U.S.C. 103(a) over the ‘666 patent in view of U.S. Patent No. 5,938,668 to Scirica et al (hereinafter “Scirica”);
- (C) Claims 31-38 have been rejected under 35 USC 103(a) over U.S. Patent No. 5,425,745 to Green (hereinafter “Green”) in view of Scirica;
- (D) Claim 39 has been rejected under 35 USC 103(a) over Green;
- (E) Claims 20, 21, 23-30, and 40 have been rejected under 35 U.S.C. 103(a) over the ‘666 patent in view of Green;
- (F) Claims 31-38 have been rejected under 35 U.S.C. 103(a) over the ‘666 patent, Green and Scirica; and
- (G) Claim 39 has been rejected under 35 USC 103(a) over the ‘666 patent and Green.

(7) ARGUMENT

(A) Claims 11-13 and 51-58 have been rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,431,666 to Sauer (hereinafter “the ‘666 patent”)

The Examiner proposes that the ‘666 patent anticipates independent claims 11, 53, 12 and 51. However, the ‘666 patent completely fails to describe an opening extending through a distal portion of the tongue, as described by claims 11 and 53-58 or provision of a guide wire tube, as is described by claims 12 and 13. In order to anticipate the claims, every limitation must be found in the cited art.

The Examiner indicates that the cavities for the ferrule holder or the proximal needle holders satisfy this limitation. However, it is noted that the opening of claims 11 and 53 are distinctly recited as separate from the ferrule holder cavity, the needle holes of the ‘666 patent are proximal, and the recitation with regard to the opening indicates that the opening goes through the tongue (i.e., it is an opening rather than a cavity) (which makes sense considering that the

specification describes use for an opening as allowing a guidewire to be threaded therethrough to facilitate placement).

Likewise, there is no guidewire tube in the '666 patent at all. Again, if a guidewire were inserted anywhere in a cavity of the '666 device, it still could not go through the device (and thus act as a guidewire).

The '666 patent also completely fails to teach a ferrule holder including projections receivable within grooves of the tongue for retaining the ferrule holder on the tongue, as is required by independent claim 51. The Examiner has completely failed to show projections of the ferrule holder received within grooves of the tongue. Contrary to the Examiner's contentions, Figure 2 of the '666 patent shows nothing of the sort. No projections, no grooves, and no projection received within a groove to hold the ferrule holder on the tongue.

Because the required limitations are not taught by the '666 patent, the rejection is in error.

(B) Claims 5-10 and 42-45 were rejected under 35 U.S.C. 103(a) over the '666 patent in view of U.S. Patent No. 5,938,668 to Scirica et al (hereinafter "Scirica")

Claims 5-10 and 42-45 all depend from independent claim 51, which claim requires ferrule holder projections. Neither the '666 patent nor Scirica describe such projections. Reference is made to section (A) above for a detailed discussion. Because claims 5-10 and 42-45 depend from independent claim 51, they are likewise patentable.

(C) Claims 31-38 have been rejected under 35 USC 103(a) over U.S. Patent No. 5,425,745 to Green (hereinafter "Green") in view of Scirica.

Claims 31-38 all depend in some fashion from independent claim 51, which requires projections for holding ferrules. The Examiner has completely failed to consider such limitations, and thus fails to even complete a prima facie case of obviousness. All elements of the claim must be considered in making such a case, and all elements must be identified in the prior art. At least for this reason, the rejection is in error.

Further, Green does not describe any such projection ferrule holders. Scirica does not describe any such projection ferrule holders. Because this limitation is lacking, a prima facie case cannot be sustained. Accordingly, this rejection is in error.

(D) Claim 39 has been rejected under 35 USC 103(a) over Green.

As with the claims cited directly above, claim 39 depends from independent claim 51, which requires projections for holding ferrules. The Examiner has completely failed to consider such limitations, and thus fails to even complete a prima facie case of obviousness. All elements of the claim must be considered in making such a case, and all elements must be identified in the prior art. At least for this reason, the rejection is in error.

Further, Green does not describe any such projection ferrule holders. Scirica does not describe any such projection ferrule holders. Because this limitation is lacking, a prima facie case cannot be sustained. Accordingly, this rejection is in error.

(E) Claims 20, 21, 23-30, and 40 have been rejected under 35 U.S.C. 103(a) over the '666 patent in view of Green.

Claims 20, 21 and 23-30 all depend in some fashion from independent claim 51, which requires projections for holding ferrules. As is noted above, the '666 patent does not teach projections receivable in grooves to hold the ferrule holder on the tongue. Also, Green does not teach such limitations (and the Examiner has not addressed such limitation with regard to Green). Accordingly, the rejections of claims 20, 21 and 23-30 are in error.

Claim 40 requires, in relevant part, that the handle's U-shaped cross section is perpendicular to the longitudinal axis of the device. This is not taught by Green.

The Examiner indicates that Figure 1 of Green shows such a cross section, but it is reiterated that the cross section is relative to the perpendicular of the devices longitudinal axis. While the device may have a U-shaped cross section relative to the longitudinal axis, it does NOT have such a cross section relative to the perpendicular of the longitudinal axis. At least for this reason, the rejection is in error.

(F) *Claims 31-38 have been rejected under 35 U.S.C. 103(a) over the '666 patent, Green and Scirica.*

Claims 31-38 all depend in some fashion from independent claim 51, which requires projections for holding ferrules. As is noted above, the '666 patent does not teach projections receivable in grooves to hold the ferrule holder on the tongue. Also, Green does not teach such limitations (and the Examiner has not addressed such limitation with regard to Green). Likewise, Scirica does not teach such limitations. Accordingly, the rejections of claims 31-38 are in error.

(G) Claim 39 has been rejected under 35 USC 103(a) over the '666 patent and Green.

Claim 39 depends from independent claim 51, which requires projections for holding ferrules. As is noted above, the '666 patent does not teach projections receivable in grooves to hold the ferrule holder on the tongue. Also, Green does not teach such limitations (and the Examiner has not addressed such limitation with regard to Green). Accordingly, the rejection of claim 39 is in error.

CLAIMS APPENDIX

5. A surgical apparatus in accordance with claim 51, the surgical apparatus further comprising:

an elongate body assembly connecting a body portion to the tongue member, and further comprising first and second elongate needles positioned at least partially within the elongate body assembly, said first needle being longitudinally movable by a first lever and said second needle being longitudinally movable by a second lever.

6. The surgical apparatus of claim 5 wherein said first and said second levers are spaced apart less than 180 degrees from each other.

7. The surgical apparatus of claim 5 wherein said first and said second levers are not diametrically positioned.

8. The surgical apparatus of claim 5 wherein the first and second elongate needles are eccentrically positioned within the elongate body assembly.

9. A surgical apparatus in accordance with claim 51, the surgical apparatus further comprising:

a body portion having first and second levers pivotally secured to the body portion, wherein the first lever is a first color to indicate its connection with a first needle, and the second lever is a second color, different than the first color, to indicate its connection with a second needle.

10. A surgical apparatus in accordance with claim 51, the surgical apparatus further comprising

a body portion having first and second levers pivotally secured to the body portion, wherein the first and second levers are mounted to a distal end of the body portion.

11. A surgical apparatus for closing a wound, the surgical apparatus comprising:

a tongue member having a distal section insertable into a wound and having an opening through a portion of said distal section; and

a face opposing the distal section of the tongue member and separated from the distal section of the tongue member by a gap, the face having an area large enough to impede further insertion of the apparatus into the wound, further comprising a sleeve holder positioned within the distal section of the tongue member, the sleeve holder including first and second sleeves disposed within the sleeve holder, said first and second sleeves being joined by a length of suture material.

12. A surgical apparatus for closing a wound, the surgical apparatus comprising:

a tongue member having a distal section insertable into a wound; and

a face opposing the distal section of the tongue member and separated from the distal section of the tongue member by a gap, the face having an area large enough to impede further insertion of the apparatus into the wound, further comprising a guide wire tube disposed through an elongate body assembly, a distal end of the guide wire tube being disposed adjacent a distal opening of the tongue member.

13. The surgical apparatus of claim 12 wherein the guide wire tube includes an opening spaced proximally the distal end thereof.

20. The surgical apparatus of claim 51, further comprising:

a body portion having a distal end and a proximal end;

a tubular portion having a distal end and a proximal end, the proximal end of the tubular portion attached to the distal end of the body portion, a distal end of the tubular portion positioned proximally of said window; and

a lever having a distal end and a proximal end, the distal end of the lever operatively coupled to the distal end of the body portion, wherein the body portion includes a longitudinal

axis and the lever includes a longitudinal axis, and further wherein the longitudinal axis of the lever is parallel to the longitudinal axis of the body portion in a closed position of the lever.

21. The surgical apparatus of claim 20 wherein the lever is actuatable to a position where the longitudinal axis of the lever is askew from the longitudinal axis of the handle body portion.

23. The surgical apparatus of claim 51, further comprising:

a body portion having a distal end and a proximal end;

a tubular portion having a distal end and a proximal end, the proximal end of the tubular portion attached to the distal end of the body portion, a distal end of the tubular portion positioned proximally of said window; and,

a lever having a distal end and a proximal end, the distal end of the lever operatively coupled to the distal end of the body portion, wherein the lever is pivotally mounted to the body portion, further comprising a link connected at a first end to the lever and at a second end to a slidable member within the body portion.

24. The surgical apparatus of claim 23 wherein movement of the proximal end of the lever towards the proximal end of the body portion forces the slidable member to move towards the distal end of the body portion.

25. The surgical apparatus of claim 24 further comprising a drive block, wherein the slidable member cooperates with the drive block to move the drive block correspondingly with the slidable member.

26. The surgical apparatus of claim 25 wherein the slidable member is a locking collar which surrounds a reduced diameter portion of the drive block.

27. The surgical apparatus of claim 25 wherein the drive block is biased proximally by a spring.

28. The surgical apparatus of claim 25 wherein the drive block includes a longitudinal opening

for frictionally receiving a proximal end of a drive tube.

29. The surgical apparatus of claim 24 wherein the proximal end of the lever is biased away from the proximal end of the body portion.

30. The surgical apparatus of claim 23 wherein movement of the proximal end of the lever away from the proximal end of the body portion forces the slidable member to move towards the distal end of the body portion.

31. The surgical apparatus of claim 30 wherein the slidable member is a needle driver.

32. The surgical apparatus of claim 31 further comprising a needle in the tubular portion, the needle movable in response to movement of the needle driver.

33. The surgical apparatus of claim 31 wherein the lever is a first lever, the link is a first link, and the needle driver is a first needle driver, the surgical apparatus further comprising a second lever having a proximal end and a distal end, the distal end of the second lever operatively coupled to the distal end of the body portion, a second link connected at a first end to the second lever and at a second end to a second needle driver within the body portion.

34. The surgical apparatus of claim 33 wherein the second needle driver is positioned proximal to the first needle driver.

35. The surgical apparatus of claim 34 wherein first needle driver receives a first needle, and the first needle driver has a longitudinal opening dimensioned to allow a second needle to pass through the first needle driver freely to the second needle driver.

36. The surgical apparatus of claim 35 wherein the second needle driver receives the second needle.

37. The surgical apparatus of claim 36 wherein the second needle driver includes an opening dimensioned to frictionally receive the second needle, the opening for receiving the second needle being smaller than the longitudinal opening in the first needle driver for passing the second needle.

38. The surgical apparatus of claim 34 wherein the first needle driver includes another longitudinal opening dimensioned to frictionally receive the first needle, wherein the longitudinal opening receiving the first needle is smaller than the longitudinal opening for passing the second needle.

39. The surgical apparatus of claim 23 wherein the slidable member includes a tab with a hole, the second end of the lever surrounding the tab and connected to the tab via a link pin inserted through the hole and through the second end of the lever.

40. A surgical apparatus comprising:

a body portion having a distal end and a proximal end;

a tubular portion having a distal end and a proximal end, the proximal end of the tubular portion attached to the distal end of the body portion; and,

a lever having a distal end and a proximal end, the distal end of the lever operatively coupled to the distal end of the body portion, wherein the lever has a generally U-shaped cross-section relative to the perpendicular of the longitude of the body portion, with a flat surface of the lever lying substantially flush with the body portion in a closed position of the lever.

42. A surgical apparatus in accordance with claim 51, the surgical apparatus further comprising:

a body portion having a distal end and a proximal end;

a tubular portion having a distal end and a proximal end, the proximal end of the tubular portion attached to the distal end of the body portion; and,

a lever having a distal end and a proximal end, the distal end of the lever operatively coupled to the distal end of the body portion, wherein the lever is a first lever, the surgical apparatus further comprising a second lever having a proximal end and a distal end, the distal end of the second lever operatively coupled to the distal end of the body portion.

43. The surgical apparatus of claim 42 wherein the second lever is angularly displaced on the body portion from the first lever.

44. The surgical apparatus of claim 43 wherein the second lever is placed less than 180 degrees from the first lever.

45. The surgical apparatus of claim 42 wherein the first lever includes a first color and the second lever includes a second color, different than the first color.

51. A surgical apparatus comprising a tip, the tip having a longitudinal axis, a distal end, and a proximal end, the tip further comprising:

a window for receiving tissue;

a first wall at a proximal end of the window, the first wall disposed at an angle to the longitudinal axis, the angle selected to impede insertion of the tip into a wound; and,

a second wall disposed at an angle to the longitudinal axis at a distal end of the window, further comprising a ferrule holder, the ferrule holder including the second wall, further comprising a tongue extending between the first and second walls, wherein the ferrule holder includes projections receivable within grooves of the tongue for retaining the ferrule holder on the tongue.

52. The surgical apparatus of claim 51 wherein the tongue includes a lip which wraps around a distal end of the ferrule holder for further retaining the ferrule holder on the tongue.

53. A tip for a surgical apparatus, the tip having a longitudinal axis, a distal end, and a proximal end, the tip further comprising:

a window for receiving tissue;

a first wall at a proximal end of the window, the first wall disposed at an angle to the longitudinal axis, the angle selected to impede insertion of the tip into a wound; and,

a second wall disposed at an angle to the longitudinal axis at a distal end of the window, further comprising a tongue having an opening through a portion of a distal tongue section, a base of the tongue forming a bottom portion of the window.

54. The tip of claim 53 wherein a distance from the first wall to the second wall at a bottom portion of the window is less than a distance from the first wall to the second wall at a top portion of the window.

55. The tip of claim 53 wherein a proximal end of the tongue includes a T-shaped extension.

56. The tip of claim 55 further comprising a face, the face including the first wall, the face positioned on a proximal portion of the tongue and distally of the T-shaped extension.

57. The tip of claim 56 wherein the face is retained on the tongue by a snap-fit connection.

58. The tip of claim 53 wherein the tongue includes a longitudinal opening having a proximal end and a distal end, the distal end of the longitudinal opening including an exit opening positioned proximally of the distal end of the tip.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None

CONCLUSION

The rejections of the claims are in error and should be reversed. If there are any charges with respect to this brief or otherwise, please charge them to Deposit Account 06-1130, maintained by the applicant's attorneys.

Respectfully submitted,

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